18885), FDA withdrew approval of NDA 0–0499 for Perandren Ointment based on the applicant's failure to submit required annual reports (section 505(e) of the act (21 U.S.C. 355(e)) and 21 CFR 314.80 and 314.81).

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that testosterone propionate 2% ointment was not withdrawn from sale for reasons of safety or effectiveness and will relist testosterone propionate 2% ointment in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to testosterone propionate 2% ointment may be approved by the agency.

Dated: October 27, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–29766 Filed 11–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0482]

Biora US, Inc.; Premarket Approval of EMDOGAIN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Biora US, Inc., West Chester, OH, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of EMDOGAIN®. After reviewing the recommendation of the Dental Products Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1996, of the approval of the application.

DATES: Petitions for administrative review by December 23, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Pamela D. Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION: On July 19, 1993, Biora US, Inc., West Chester, OH 45069, submitted to CDRH an application for premarket approval of EMDOGAIN®. The device is a bone filling and augmentation device and is indicated for use as an adjunct to periodontal surgery for topical application onto exposed root surfaces to treat intrabony defects without furcations resulting from loss of tooth support due to moderate or severe periodontitis. EMDOGAIN® is to be used with the supplied vehicle solution of propylene glycol alginate.

On February 27, 1996, the Dental Products Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before December 23, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 24, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–29765 Filed 11–20–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, December 12, 1996, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 9:00 a.m. to adjournment. The topics proposed for discussion include (1) Clinical Center Update; (2) Report from the Clinical Research Panel; (3) Discussion of Small Business Innovation Research and Small Business Technology Transfer Grants; and (4) Report from the Research Integrity Panel. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Program Assistant, Office of the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than December 9, 1996.

Dated: November 18, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96–29813 Filed 11–20–96; 8:45 am]

BILLING CODE 4140–01–M